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09/222,123 12/29/98 RAY

R 6328-21

EXAMINER

IM22/0412

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ART UNIT

PAPER NUMBER

1743

DATE MAILED:

04/12/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/222,123

Applicant(s)

Ray et al.

Examiner

John C. Kim

Group Art Unit

1743



- ☐ Responsive to communication(s) filed on \_\_\_\_\_
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

- ☒ Claim(s) 1-20 is/are pending in the application.
- Of the above, claim(s) 13-18 is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-12, 19, and 20 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☒ Claims 1-20 are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☒ The drawing(s) filed on Dec 29, 1998 is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- ☒ Notice of References Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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## DETAILED ACTION

### *Election/Restriction*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-12 and 19-20, drawn to a device and kit for remote-site biological collection, classified in class 422, subclass 939.
  - II. Claims <sup>13-18</sup>~~17-20~~, drawn to a method of collection and transport of a biological sample, classified in class 436, subclass 178
2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the process can be practiced by another materially different apparatus such as a urine collection cup.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
4. During a telephone conversation with Mr. Stanley Kim on April 6, 2000, a provisional election was made without traverse to prosecute the invention of Group I,

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claims 1-12 and 19-20. Affirmation of this election must be made by applicant in replying to this Office action. Claims 13-18 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### ***Drawings***

6. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

#### ***Specification***

7. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

#### ***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

9. Claims **1-4, 5-7 and 10-12** are rejected under 35 U.S.C. 102(b) as being anticipated by Lee 4,260,392.

Lee 4,260,392 teaches a device for the collection of albumin from urine, comprising:  
a relatively rigid strip (support 11 of plastic or glass) forming a handle member having a handle end and a collection end comprising a collection pad 13 made of an adsorbent PVA gel which is non-reactive for the purposes of a rapid, on-site diagnostic test;

and where the strip has an aperture formed in the collection end (well 12) which exposes a portion the collection pad 13 (FIGS. 1, 15, col. 3, lines 60-68, col. 4, lines 38-39, col. 5, lines 62-67, col. 9, lines 6-16).

Lee 4,260,392 also teaches a device where there is a plurality of collection pads and apertures (FIG. 6).

Thus claims 1-4, 5-7 and 10-12 are anticipated by Lee 4,260,392.

10. Claim **19** is rejected under 35 U.S.C. 102(e) as being anticipated by Ray et al. 6,036,659.

Ray et al. 6,036,659 teach a kit for remote-site collection of a biological sample, comprising:

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a relatively rigid strip 13 forming a handle member having a handle end 11 and a collection end 14 and a collection pad 12 (FIG. 1), and wherein the strip has an aperture formed at the collection end which exposes a portion the collection pad; and

an information card for providing information about the patient (FIG. 4A-G; cls. 24-25).

11. Thus claim 19 is anticipated by Ray et al. 6,036,659.

***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. Claims **1, 8 and 9** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee 4,260,392.

Lee 4,260,392 teaches a device for the collection of albumin from urine, comprising:

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a relatively rigid strip (support 11 of plastic or glass) forming a handle member having a handle end and a collection end comprising a collection pad 13 made of an adsorbent PVA gel which is non-reactive for the purposes of a rapid, on-site diagnostic test;

and where the strip has an aperture formed in the collection end (well 12) which exposes a portion the collection pad 13 (FIGS. 1, 15, col. 3, lines 60-68; col. 4, lines 38-39, col. 5, lines 62-67, col. 9, lines 6-16).

Lee 4,260,392 fails to teach incorporating bovine serum albumin(BSA) in the collection pad.

It is well known in the art to immobilize BSA in the matrix of a collection pad. It would have been obvious to one of ordinary skill in the art to do so because it is also well known that BSA is very useful in preserving dried blood or urine samples.

15. Claim **20** is rejected under 35 U.S.C. 103(a) as being unpatentable over Ray et al. 6,036,659 in view of Brown, Jr. 5,921,396.

Ray et al. 6,036,659 teach a kit for remote-site collection of a biological sample, comprising:

a relatively rigid strip 13 forming a handle member having a handle end 11 and a collection end 14 and a collection pad 12 (FIG. 1), and wherein the strip has an aperture formed at the collection end which exposes a portion the collection pad;

an information card for providing information about the patient; and

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a packing means for transporting the collected sample (FIG. 4A-G; cls. 24-25).

Ray et al. 6,036,659 fail to provide a urine collection cup in their kit.

Brown, Jr. 5,921,396 teaches a combination urine collection kit and shipping means, wherein the kit comprises a sample collection tubes (12,14) and a urine collection cup 40 (abstract; FIGS. 1-22).

It would have been obvious to one of ordinary skill in the art to provide a urine collection cup for Ray's kit because a collection cup would allow for a midstream urine collection and the ability to dip the strip into the cup rather than attempting to catch the urine stream with the strip. This leads to a more sanitary collection process and reduces the chance of contaminating the strip.



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***Conclusion***

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.


Hansen et al. 5,523,055 teach a device for the collection, transporting and testing urine sample, comprising a rigid handle with a collection pad.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner John C. Kim whose telephone number is (703) 306-5414.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Jill Warden, can be reached at (703) 308-4037. The fax number for the organization where this application or proceeding is assigned is (703) 305-7718.

JKIM

April 10, 2000

  
Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700